

Sweety

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**Email:** **sweety.388058@2freemail.com**

**PROFESSIONAL PROFILE - INDEPENDENT CONSULTANT**

***Dedicated Regulatory Specialist*** *with* ***over 9 years of experience*** *in:*

***~Regulatory Documentation ~Regulatory Submissions & Approvals ~Regulatory Requirements***

***~eCTD Submissions ~Query Management ~Extedo – eCTDmanager Software ~Liaison & Coordination ~Compliance ~Team Lead***

* Experienced in ***eCTD publishing*** of Initial Marketing Authorisation Application, ***eCTD and NeeS*** (Non-eCTD electronic Submissions) variation packages, ***Veterinary Non-eCTD electronic Submission*** (VNeeS) dossiers, ***RFIs publishing*** along with transfer of ***Marketing Authorisation Holder*** (MAH) submissions
* Expertise in dossiers authoring to various ***Asian, African, Common wealth of Independent States (CIS), and Latin American countries*** as per respective country guidelines, CTD and ACTD conversions and label reviews of investigational medicinal products
* Skilled at leading, managing, and providing ***strategic direction to regulatory team*** to successfully develop and execute submission output as per the client aspects
* Demonstrated abilities in ***reviewing and generating label reports of investigation medicinal products*** to ensure compliance as per ***regulatory requirements***
* Pivotal in acting as the link between the ***company and the local regulatory authorities*** on matters relating to the quality, safety and efficacy issues of drugs

**CAREER REVIEW**

**Jan to Dec 2019: Pursuing Distance Learning in Advance Certificate Program in Digital Marketing from NMIMS, Global Access School For Continuing Education, Mumbai, India**

**Feb 2019: Enrolled in “Beginners Arabic Course” (Speaking and Writing) from St. Mary’s Church, Dubai.**

**Jan 2018: Completed Certificate Program in Digital Marketing from NMIMS Global Access School For Continuing Education, Mumbai, India**

This course enables:

* To know the basics of online marketing and strategies
* Knowledge in key areas of marketing (blogging, SEO, social media, content marketing, email marketing etc.)
* To work on my travel blog

**Jan 2017 to till date: Independent Consultant Regulatory Affairs-Freelance (Relocated to Dubai, UAE)**

* CMC authoring
* Documents readiness for eCTD submissions
* Submission reviewing

**May 2012 to Oct 2015: – Genpact Pharmalink, Mumbai, India as Lead Consultant**

* Accountable for submitting eCTD, Non e-CTD electronic submission (NeeS), and Veterinary Non e-CTD Electronic Submission (VNeeS) publishing in realistic timeline through “Extedo – eCTDmanager Software”:
* Published initial MAAs for EU countries (DCP procedure), Australia and Saudi Arabia
* Published single and grouped variation packages in NeeS for EU and Switzerland
* Published MRP assessment report and Line Extension submissions for EU countries
* Published NeeS and VNeeS RFIs for EU countries
* Published VNeeS dossier for EU countries
* Published transfer of Marketing Authorization Holder submissions
* Reviewed and generated label reports of investigation medicinal products (IMP) to ensure compliance as per regulatory requirements of over 70 countries worldwide
* Worked on compliance and dossier authoring from ICH CTD to ASEAN CTD
* Communicated with various clients and countries regulatory coordinators via emails or telephone for resolving queries

**Nov 2010 to Apr2012: Eurolife Healthcare Pvt. Ltd., Mumbai, India as Executive – Regulatory Affairs**

**Oct 2009 to Oct 2010: Ciron Drugs & Pharmaceuticals Pvt. Ltd., Mumbai, India as Executive – Regulatory Affairs**

**Jul 2006 to Sep 2009: Cipla Ltd., Mumbai, India as Trainee to Executive – Regulatory Affairs**

***Key Deliverables:***

**Submissions & Approvals**

* Managed submission and approval of dossiers as per country guideline for various African, Asian and Latin American countries including tender requirements
* Adept at managing submissions and approvals of CTD, ACTD, and country guideline dossiers for various countries including Russia, Ukraine, Philippines, Vietnam, Cambodia, Myanmar, Zambia, Nigeria, Uganda, Gabon, Ivory coast, Mali, Sri Lanka, Dominican Republic, Peru, El-Salvador, Guatemala etc.
* Reviewed mock ups of packaging labels and patient information leaflets to ensure compliance as per regulatory requirements of respective countries
* Reviewed and approved eCTD submissions in accordance to each market regulations, mostly the EU region
* Prepared Quality Overall Summary (QOS) for drug substance/product

**Liaison & Coordination**

* Communicated with countries regulatory coordinators and responding queries for different regulatory health authorities
* Liaising with concerned department for technical data and samples requirement for registration purposes
* Coordinated with other Team leaders, Project managers, Head RA for the development of productivity and qualities
* Monitored the team to update the regulatory requirements database for each market

**Apr 2005 to June 2006: ICICI Bank, Mumbai – Telecaller (Part time)**

* Prepared for entrance examinations
* Worked as a Telecaller in credit card department for collection of due payment.
* Back office data entry

**Jul 2004 to Mar 2005: Pharmacist**

* Worked as a Trainee Pharmacist in local Pharmacy

**ACADEMIC CREDENTIALS**

**Bachelors in Pharmaceutical Science from SIPS, Biju Pattnayak University, India in 2004**

***Certifications / Trainings:***

* Attended the following hands-on trainings:
* eCTD publishing technical training on eCTD/NeeS submission by using eCTDmanager-Extedo
* eCTD publication for technical training on publishing of eCTD by using Lorenz software

***Memberships:***

* Registered Pharmacist with Jharkhand (India) State Pharmacy Council

**SKILLS**

* Self-discipline, Team player, Task oriented and cooperative
* Positive attitude, good listener and learner
* Analytical and problem solving skills
* High affinity to deal with Extedo – eCTDmanager Software
* Good ability to making healthy professional relationship with client and colleagues

**PERSONAL DETAILS**

**Date of Birth:** 31st January, 1981 | **Nationality:** Indian | **Languages known:** English, Hindi, Oriya, Marathi and Bengali| **Marital Status:** Married |